7.5 GEL FOR DIRECT APPLICATION FORMULATION (GD)

Introduction

Gel for direct application (GD) is the designation for a gel-like preparation, intended to be applied undiluted. A gel for direct application consists of one or more active ingredients, a structuring agent and other formulants if appropriate.

*Note for preparation of draft specifications. Do not omit clauses or insert additional clauses, nor insert limits that are more lax than those than given in the guidelines, without referring to section 4. From the “Notes” provided at the end of this guideline, incorporate only those which are applicable to the particular specification.*

… [ISO common name] (AGROCHEMICAL) GEL FOR DIRECT APPLICATION

[CIPAC number]/GD (month & year of publication)

7.5.1 **Description**

The material shall consist of technical .....[ISO common name], complying with the requirements of FAO/WHO specification ....., in the form of ..... (see Section 4.2), homogenized in suitable solvents, together with any other necessary formulants. It shall be in the form of a clear or opalescent gel, free from visible suspended matter and sediment, to be applied directly (without prior dilution in water).

7.5.2 **Active ingredient**

7.5.2.1 **Identity tests** (Note 1)

The active ingredient(s) shall (each) comply with an identity test and, where the identity remains in doubt, shall comply with at least one additional test.

7.5.2.2 … **[ISO common name] content** (Notes 1)

The … [ISO common name] content shall be declared (g/kg or g/L at 20 ± 2 °C, Note 2) and, when determined, the average content measured shall not differ from that declared by more than the appropriate tolerance given in the table of tolerances, Section 4.3.2.

7.5.3 **Relevant impurities**

7.5.3.1 **By-products of manufacture or storage** (Note 3), if required

Maximum: …% of the … [ISO common name] content found under 7.5.2.2.

7.5.3.2 **Water** (MT 30.6) (Note 4), if required

Maximum: ... g/kg

7.5.4 **Physical properties**

7.5.4.1 **Appearance**

Homogeneous formulation, no phase separation is observed.

7.5.4.2 **Acidity** and/or **Alkalinity** (MT 191) or pH range (MT 75.3) (Note 5), if required

Maximum acidity: .... g/kg calculated as H2SO4

Maximum alkalinity: .... g/kg calculated as NaOH

pH range .... to ....

7.5.5 **Storage stability**

7.5.5.1 **Stability at 0 °C** (MT 39.3)

After storage at 0 ± 2 °C for 7 days, the volume of solid and/or liquid which separates shall not be more than 0.3 mL

7.5.5.2 **Stability at elevated temperature** (MT 46.4)

After storage at 54 ± 2 °C for 14 days (Note 6), the determined average active ingredient content shall not be lower than … relative to the determined average content found before storage (Note 7) and the product shall continue to comply with the clauses for:

- by-products of manufacture or storage (7.5.3.1),

- appearance: no phase separation (7.5.4.1),

- acidity/alkalinity/pH range (7.5.4.2),

as required.

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Note 1 Method(s) of analysis must be CIPAC, AOAC or equivalent. Where methods have not yet been published, full details and appropriate method validation data must be submitted to FAO/WHO by the proposer.

Note 2 If the buyer requires both g/kg and g/L at 20 °C, then in case of dispute the analytical results shall be calculated as g/kg.

Note 3 This clause should include only relevant impurities and the title should be changed to reflect the name of the relevant impurity. Method(s) of analysis must be peer validated.

Note 4 This clause is not appropriate for formulations formulated in water.

Note 5 The method to be used shall be stated. If several methods are available, a referee method shall be selected.

Note 6 Unless other temperatures and/or times are specified. Refer to Section 4.6.2 of this manual for alternative storage conditions.

Note 7 Samples of the formulation taken before and after the accelerated storage stability test may be analysed concurrently after the test in order to reduce the analytical error.